

**REMARKS**

**I. Status of the Claims**

Claims 1-7 and 9-19 are pending in this case, with claim 1 being the sole independent claim. In the Office Action dated August 11, 2006, claims 1-6, 9-14, and 16-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,221,046 to Burroughs et al. ("Burroughs") and claims 7 and 15 were rejected under 35 U.S.C. § 103 as being obvious over Burroughs in view of U.S. Patent Application Publication No. 2002/0165499 A1 to Slate et al. ("Slate"). These rejections are traversed for the reasons set forth below.

**II. Claim 1 is Not Anticipated by Burroughs**

Independent claim 1 recites a drive mechanism comprising, *inter alia*, a housing having internal and external threads, a piston rod threadedly engaged with the internal thread of the housing, a drive sleeve located between the housing and the piston rod, and clutch means located between the drive sleeve and the dose dial sleeve.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Finally, "[t]he elements must be arranged as required by the claim." M.P.E.P. § 2131.

Rejecting claims 1-6, 9-14, and 16-19, the Office Action of August 11, 2006

alleges that:

Burroughs discloses a drive mechanism 20 comprising a housing 24, 26 having internal and external threads, a piston rod 210, a dose dial sleeve 34, a drive sleeve 38, and a clutch means (Col. 2, lines 51-55). The device is a pen type injector device comprising a needle 222. The device can be used to deliver insulin.

(August 11, 2006, Office Action, Page 2.) The reference numbers from Burroughs indicated in the Office Action, however, do not correspond to the particular features recited in claim 1.

For example, reference no. 20 in the figures of Burroughs refers to a whole injection device and not a drive mechanism as claimed. In addition, the housing of claim 1 includes internal and external threads, whereas elements 24 and 26 of Burroughs both omit at least the feature of external threads (as can be seen in FIGS. 2, 3, and 5 of Burroughs).

Regarding the piston rod of claim 1, the Office Action refers to reference no. 210 of Burroughs, which is disclosed as a "piston 210 of cartridge 40." (See, e.g., Burroughs at column 9, line 34 and FIG. 1.) The piston rod recited in claim 1 includes the limitation of being threadedly engaged with the internal threads of the housing. Therefore, the piston 210 of Burroughs cannot correspond to the claimed piston rod at least because element 210 of Burroughs is not threadedly engaged with elements 24 or 26 of Burroughs, which the Office Action relies upon as corresponding to the claimed housing. Accordingly, piston 210 cannot be relied upon as corresponding to the claimed piston rod.

Furthermore, the Office Action points to the lead screw (reference no. 38) of Burroughs as corresponding to the claimed drive sleeve of claim 1. However, as required in claim 1, the drive sleeve must be located between the housing and the piston rod. As seen in FIG. 1 of Burroughs, the lead screw (reference no. 38) is not disposed in a location between the housing and the piston rod as required by claim 1.

Additionally, the alleged clutch means of Burroughs (disclosed in column 2, lines 51-55 of Burroughs, according to the November 11, 2006, Office Action) is not located between a drive sleeve and a dose dial sleeve, as required by claim 1. Instead, the clutch described in Burroughs is located between the dial mechanism (reference no. 34) and the nut (reference no. 36). See, e.g., Burroughs at column 11, lines 27-30 and column 12, lines 15-18.

Accordingly, for at least the reasons presented above, Burroughs cannot anticipate independent claim 1. Therefore, Applicants respectfully request that the rejection of independent claim 1 and its dependent claims 2 -6, 9-14, and 16-19 be withdrawn.

### **III. Claim Rejections - 35 U.S.C. § 103(a)**

As noted above, the Examiner rejected claims 7 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Burroughs in view of Slate. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation...to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, and not based on applicant's disclosure." M.P.E.P. § 2143, quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden of establishing a *prima facie* case of obviousness is on the Examiner.

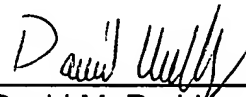
As noted above in the discussion of the Section 102 rejections, Burroughs fails to teach each of the recitations of independent claim 1. Regarding the Section 103 rejections, the Office Action does not rely on Slate to cure the above-noted deficiencies of Burroughs. Further, slate does not remedy these deficiencies. A *prima facie* case of obviousness therefore has not been established with regard to any of the pending claims. For at least these reasons, Applicants request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,  
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